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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,754	07/12/2006	Marc Karel Jozef Francois	PRD2166USPCT	1592

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EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
4121	

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03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,754	FRANCOIS ET AL.	
	Examiner	Art Unit	
	ADAM C. MILLIGAN	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-13 are currently pending.

Election/Restrictions

Applicant's election with traverse of Group 1 in the reply filed on 3/16/2009 is acknowledged. The traversal is on the grounds that the oral solution of Group I and the method of making of Group II overlap in subject matter, the search for the Group I will overlap with search for Group II, and there is no undue burden for searching Groups I and II together. This argument is not found persuasive because the standard for proper restriction in a national stage application submitted under 35 U.S.C. 371 is not dependent on search burden or overlapping scope.

The standard for restriction of a national stage application submitted under 35 U.S.C. 371 is set forth in 37 CFR 1.457(a). 37 CFR 1.457(a) states that a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As

demonstrated in the requirement for restriction, the common technical feature of Groups I and II is also present in the prior art. There is no 'special' technical feature between Groups I and II, so unity is broken and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim 13 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election with traverse of a species in the reply filed on 3/16/2009 is acknowledged. The requirement for an election of species is hereby withdrawn.

Priority

This application claims the benefit of priority under 35 U.S.C. § 119 (a)-(d) based on PCT/EP2005/050181, filed January 18, 2005, and EPO 04100177.7, filed January 18, 2004. Receipt is acknowledged of papers submitted under 35 U.S.C. 119 (a)-(d) which papers have been placed of record in the file.

All claims receive a priority date of January 18, 2004.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/13499 (Published May 9, 1996; Provided by Applicants) in view of United States Patent Publication 2002/0147201 (Published October 10, 2002) and Basit et al. (The Effect of Polyethylene Glycol 400 on Gastrointestinal Transit: Implications for the Formation of Poorly Water Soluble Drugs, Pharmaceutical Research, Volume 18, No. 8, 2001).

With regard to Claim 1, WO 96/13499 teaches an oral solution comprising 1 mg/ml of mitratapide (Page 17, Compound No. 22), a solvent (Page 26, Example 8), and sucrose as a taste modifying agent (Page 26, Example 8). Additional ingredients may be included to aid in the solubility of mitratapide (Page 10, Line 18).

WO 96/13499 does not teach the incorporation of an antioxidant or specific compounds which will increase the solubility of the mitratapide active agent.

However, US 2002/0147201 teaches a means for increasing the solubility of active agents (Abstract). One way to increase active agent solubility is to add a

plasticizer such as polyethylene glycol (PEG) to the composition (Paragraph 64). After achieving the desired solution, it is important to keep the solution from degrading in any way. Commonly, butylated hydroxyanisole (BHA), an antioxidant is used at 0-15% by weight to stabilize a composition (Paragraph 76). If the composition is for oral administration, it should have a preferable taste. Taste modifying agents are commonly employed for this purpose and may be in the form of sweeteners such as sucrose or sucralose at 0 to 10% by weight (Paragraph 61).

Basit teaches that PEG 400 is a particularly preferred solubility enhancer for poorly water-soluble drugs because in addition to its superior ability to increase solubility of such drugs, PEG 400 concurrently reduces gastrointestinal transit time (Page 1149, Column 2). Therefore PEG 400 is not only an inert pharmaceutical excipient (Page 1149, Column 2), but also has an effect on the bioavailability of the co-administered drug (Page 1149, Column 2).

With regard to Claims 1 and 8-10, US 2002/0147201 teaches the incorporation of the antioxidant BHA at 0-15% by weight in order to stabilize the solution (Paragraph 76).

With regard to Claims 2 and 3, US 2002/0147201 teaches the incorporation of polyethylene glycol in order to increase the solubility of the mitratapide (Paragraph 64). Basit teaches additional benefits to choosing PEG 400 over other solvents (Page 1149, Column 2).

With regard to Claims 4-7, US 2002/0147201 teaches that sucralose, an intense sweetener, can be used as a sweetening agent in place of sucrose at 0 to 10% by weight (Paragraph 61).

With regard to Claims 11 and 12, the instant specification teaches that mitratapide has a solubility of 24.8 mg/ml in PEG 400. Upon adding PEG 400 to the composition and thus increasing its solubility, it would be obvious to increase the concentration of mitratapide in the oral solution so as to reduce the volume of the other ingredients necessary to obtain the desired effect. US 2002/0147201 teaches incorporation of sucralose at 0 to 10% by weight (Paragraph 61), BHA at 0-15% by weight (Paragraph 76), and PEG. Basit specifies that PEG 400 has additional beneficial qualities for drug ingestion (Page 1149, Column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to be motivated to combine the teachings of WO 96/13499 with US 2002/0147201 and Basit because WO 96/13499 teaches that additional ingredients which increase the solubility of mitratapide are preferable, US 2002/0147201 teaches methods of increasing solubility and bioavailability of an active drug including the incorporation of PEG into the composition, and Basit specifies that PEG 400 has unique preferable qualities over other solubility enhancing agents.

Further, the inventors possessed a reasonable expectation of successfully creating a more concentrated upon mitratapide composition upon choosing to modify the oral solution taught in WO 96/13499 by using a known method of increasing solubility.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571) 270-7674. The examiner can normally be reached on Monday through Thursday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan, can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A.C.M./
Art Unit 4121

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4121